



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/820,581

04/07/2004

Mark E. Deem

17315-002002

8576

20985 7590 10/29/2007

FISH & RICHARDSON, PC

P.O. BOX 1022

MINNEAPOLIS, MN 55440-1022

EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

10/29/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/820,581

Applicant(s)

DEEM ET AL.

Examiner

Lindsey Bachman

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 23-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 23-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to Applicant's amendment filed on 21 August 2007.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 11-16, 18, 20, 21, 24, 26, 27, 30, 32 and 33 are rejected under 35

U.S.C. 102(e) as being anticipated by Oz, et al. (US Patent Number 6,269,819).

Claim 11 and 21 and 27: Oz'819 discloses a method of repairing a heart valve by advancing a catheter (column 6, lines 29-34) through a patient's vasculature (column 8, lines 19-21) having an annuloplasty device releasably attached (column 2, lines 47-54). The annuloplasty device (102 in Figure 13, for example) is deployed to hold the leaflets of the heart valve together and reduce regurgitation (column 2, lines 47-54). Holding the valve leaflets together also modifies the spatial relationship between first and second valve leaflets to reduce regurgitation of the heart valve.

Claim 12, 13, 14, 15, 16, 26, 33-35: Oz'819 discloses modifying the spatial relationship between the leaflets by clipping opposed points along the leaflets together (column 5, lines 46-56 and Figure 13). Further, regarding Claim 34, it is known that

chordae are part of the leaflets, therefore, the opposed chordae are linked when the opposed leaflets are attached.

Claim 18, 24, 30: Oz'819 discloses that the structure can be deployed on the atrial side of the annulus (column 7, lines 51-58).

Claim 20: Oz'819 discloses advancing the catheter through the interatrial septum of the heart (column 8, lines 28-30).

Claim 32: Oz'819 discloses that the fastener clips will be made out of nitinol, stainless steel or titanium, which are not bioabsorbable materials, so they will be in place permanently (column 5, lines 14-17).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1-9, 11, 17, 19, 21, 23, 25, 27, 28, 29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boretos et al (US Patent 4,056,854) in view of Carpentier et al (US Patent 5,061,277).

Claim 1, 2, 3, 5, 11, 17, 19, 21, 23, 25, 27, 28, 29 and 31: Boretos'854 teaches a method of modifying a heart valve by advancing a catheter through the patient's vasculature (column 3, lines 20-29). A first structure is attached to the catheter (column

Art Unit: 3734

2, lines 22-27). Boretos'854 teaches deploying the first structure near the annulus of the heart valve (column 3, lines 29-34).

Boretos'854 does not teach deploying a second structure (claim 1), nor does Boretos'854 teach that the first structure is a ring (claim 2).

Carpentier'277 teaches deploying an annuloplasty ring (11) near the annulus of a heart valve and securing it with a second member (sutures 45; column 4, lines 33-42). The second member holds the leaflets of the valve together to reduce regurgitation (column 4, lines 40-42). The ring shortens/tightens the annulus in order to reduce regurgitation (column 4, lines 43-57) which in turn holds the valve leaflets closer together because they are attached to the annulus which is being reduced in circumference. It would have been obvious to one skilled in the art at the time the invention was made to modify the method taught by Boretos'854 with the method taught by Carpentier'277 because it is advantageous to perform heart surgery percutaneously since it reduces the likelihood of complications and death. Further, it is obvious that known work in one field of endeavor (percutaneous placement of artificial valves) prompt variations of it in a related field of endeavor (percutaneous placement of annuloplasty rings) based on design incentives (reduce risk for the patient, and faster recovery) if variations would have been predictable to one of ordinary skill in the art.

Claim 4: Boretos'854 teaches deploying the structure on the atrial side of the annulus (column 3, lines 20-22).

Claim 6-9: The leaflets are held together in the method taught by Carpentier'277 by permanently attaching opposed points on the valve leaflets together (column 4, lines 33-42). This attachment is performed by suturing. The leaflets are attached to chordae.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boretos'854 in view of Carpentier'277, as applied to Claim 1, in further view of Oz, et al. (US Patent Number 6,269,819).

Boretos'854 in view of Carpentier'277 do not disclose crossing the interatrial septum.

Oz'819 discloses advancing the catheter through the interatrial septum of the heart (column 8, lines 28-30) while modifying a heart valve. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method taught by Boretos'854 in view of Carpentier'277, by crossing the interatrial septum as taught by Oz'819 because this is a known method for percutaneously accessing the heart's valves.

Claims 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oz'819, as applied to Claim 27, in further view of Garrison et al. (US Patent 5,972,030).

Oz'819 teaches the limitations of Claim 34-35, except for directly linking opposed chordae.

Garrison'030 teaches that it is well known in the art to combine the use of an annuloplasty ring with other methods of correct a valve, including attaching opposed chordae (column 1, line 42 to column 2, line 6) in order to contract and stabilize the

valve annulus. It would have been obvious to one skilled in the art at the time the invention was made to modify the method taught by Oz'819 by combining it with the methods taught by Garrison'030 in order to repair two different damaged portions of the valve.

Response to Arguments

Applicant's arguments with respect to Claims 1-10 and 34 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed 21 August 2007 with respect to Claims 11-21, 23-35 have been fully considered but they are not persuasive. Applicant argues that Oz does not disclose an annuloplasty device. According to *The American Heritage® Stedman's Medical Dictionary*. Retrieved 16 October 2007, from Dictionary.com website:

Annuloplasty – Surgical reconstruction of an incompetent cardiac valve.

With this definition in mind, an annuloplasty device is not necessarily a ring, but any device that aids in the reconstruction of a faulty valve. Since Oz discloses a device that aids in reconstructing a faulty valve, it is an annuloplasty device and meets the limitations of the claim.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is 571-272-

Art Unit: 3734

6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

lb

A handwritten signature in black ink, appearing to read "M J Hayes", with a stylized flourish at the end.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER